

REMARKS

Status of the Claims

As set forth in the Office Action Summary, Claims 1-7, 9, 10, 12-16, 18 and 19 are pending.

Claims 1 and 7 are amended herein to recite that the bioparticles are exogenic. Basis for these amendments may be found throughout the specification as-filed, especially at page 2, at lines 23-29 (stating that the present invention may be used to introduce exogenic materials); page 1, lines 11-14 (stating that in order to introduce a substance which is not desirable to the target organism, chemical or physical treatment of the target cell is necessary). Claim 1 is also amended to recite that bioparticles are present in the sample. Support may be found throughout the specification and at the preamble and third paragraph of claim 1, as well as page 8, lines 12-14, of the present specification, stating that "[A]s long as the cell envelope is open, the molecule which is to be transformed should be introduced into the cell."

Thus, no new matter is submitted herein.

Entry of the foregoing, reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. §1.112, are respectfully requested in light of the remarks which follow.

Rejections Under 35 U.S.C. § 102

Claims 1, 2, 3, 7, 9, 10, 12, 16, 18 and 19 stand rejected under 35 U.S.C. § 102(b) as purportedly anticipated by Gordon (U.S. Patent No: 4,889,120) ("Gordon").

To anticipate a claim, a single prior art reference must teach each and every element of the claimed invention. See M.P.E.P. § 2131; *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986).

Applicants submit that Gordon fails to recite every element of the presently claimed invention. The claims are amended herein to recite that the bioparticles, as used in the present methods, are exogenic, *i.e.*, foreign. In contrast, the only molecules that may be transported into cells in Gordon are transferred from one cell to another by cell fusion, as noted by the Office. During cell fusion, two cells fuse

together and the contents of each cell are mixed with each other forming a new larger cell. Thus, there can be no introduction of exogenous material by way of cell fusion.

Further, Gordon fails to disclose that the magnetically susceptible particles are used to transport a foreign molecule into each separate cell in the tissue, which is the object of the present methods. Gordon describes the creation of connections between blood vessels and other biological structures by the application of electromagnetic energy. Thus, the purpose of the teachings of Gordon is not to introduce a foreign particle into each cell. Gordon also fails to describe where particles go after injection.

In the outstanding Office Action, the Office states that the structures, such as a vessel or an artery vein fall under the wording "organelles at a sub-cellular level". Applicants respectfully disagree, and in support provide herewith a definition of an organelle from the Oxford Dictionary of Biochemistry, stating that an organelle is a discrete structure in a unicellular organism, or in an individual cell of a multi-cellular organism, that is adapted and/or specialized for the performance of one or more vital functions. The organelles of Gordon would have to originate from inside one of the cells undergoing cell fusion.

The Office further states that fusion at cellular level includes the formation of pores. Applicants respectfully disagree. Gordon fails to disclose anything regarding the formation of pores. Thus, the skilled artisan would refer to standard definition of cell fusion. Using the standard definition of cell fusion, attached hereto as cited in the Oxford Dictionary of Biochemistry, cell fusion is the formation of a single hybrid cell containing the nucleic and cytoplasm from different cells. In order for cell fusion to take place between two cells, the two cells must come very close to each other so that their membranes, respectively, are entirely in contact with each other. If close enough, the membranes of the two cells form one single membrane enclosing both cells. Force is usually needed to effect cell fusion, as cells repel each other. However, Gordon does not explain how the cell fusion takes place or what causes it. The only place where this is mentioned in Gordon is at column 8, lines 13-16.

Applicants emphasize that in the case of cell fusion, permanent openings are created between the cells as the cells fuse, to form one single membrane. In the

present invention, temporary openings that are formed which make it possible for the foreign bioparticles to be introduced into the cells present in the sample.

Furthermore, in the case of cell fusion, at least two cells must always be present in order to make the fusion possible. However, in the case of the present invention it is possible to introduce a foreign bioparticle only into one cell. Thus, cell fusion is a totally different mechanism compared to the mechanisms that take place in accordance with the present invention, which use a magnetic field with alternating field direction causes heating of each magnetically susceptible particle and the medium in close vicinity to the particle induce temporary opening in the cells which make it possible for foreign bioparticles to get introduced into the cells.

Finally, the Office states that the field strength of Gordon would be the same as the present invention because the current level and frequency in Gordon are within the same range. Applicants disagree, noting that there are several further features that must be known in order to determine the field strength from the current level and frequency, including the length of the magnetic coil, the geometric dimension of it and the number of turns. These are not addressed by Gordon.

In summary, Gordon fails to recite each element of the present invention. In the case of cell fusion there is no introduction into the cells of foreign material/molecules from the outside environment where the cells reside. With cell fusion, the cells do get new contents from each other, but only in the form of exchange of intracellular contents from other cells. Thus, the original cells do not exist anymore in their original form. In contrast, with the present invention, a predetermined exogenic bioparticle is transported into the cells present in the sample. The bioparticle to be transported into the cells is not previously found within the cells, the extracellular fluid, or cell culture medium. The pores that are formed are temporary, not permanent as in the case of cell fusion. Applicants request that the rejection under 35 U.S.C. § 102 be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 4-6 and 13-15 are rejected under 35 U.S.C. § 103(a) as unpatentable over Gordon (U.S. Patent No: 4,889,120) in view of Gray et al. (U.S. Patent No. 6,149,576).

In order to establish a case of *prima facie* obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. See M.P.E.P. § 2142. Applicants respectfully submit that these criteria have not been met in the present Office Action.

As noted above, Gordon fails to recite each element of the present invention, as Gordon does not disclose the introduction of exogenic bioparticles or that the magnetically susceptible particles are used to transport a foreign molecule into each separate cell in the tissue. In the case of cell fusion there is no introduction into the cells of foreign material/molecules from the outside environment where the cells reside. With cell fusion, the cells do get new contents from each other, but only in the form of exchange of intracellular contents from other cells. Thus, the original cells do not exist anymore in their original form. In contrast, with the present invention, a predetermined exogenic bioparticle is transported into the cells present in the sample. The bioparticle to be transported into the cells is not previously found within the cells, the extracellular fluid, or cell culture medium. The pores that are formed are temporary, not permanent as in the case of cell fusion.

Gray is cited as purportedly disclosing the use of two coils to produce an alternating magnetic field to a biological specimen. However, Gray does not remedy the deficiencies of Gordon.

Because the cell fusion method of Gordon is different from that of the present invention, it would not be obvious to the skilled artisan to modify Gordon in view of Gray and arrive at the present invention. Nor would there be an expectation of success in this regard, using the cell fusion methods of Gordon. Applicants request that the rejection under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this paper, or the application in general, the Examiner is respectfully urged to telephone Applicants' undersigned representative so that prosecution of this application may be expedited.

Respectfully submitted,

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